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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,154	06/22/2001	Ramesh Wariar	112713-131	8167

29200 7590 09/29/2005

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EXAMINER	
BIANCO, PATRICIA	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,154	WARIAR ET AL.	
	Examiner	Art Unit	
	Patricia M. Bianco	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-14,17-21,23-27,29,30 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-14,17-21,23-27,29,30 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/02/05 has been entered.

Response to Amendment

Applicant filed an amendment 6/21/05 in response to the Final Rejection. The amendment has been entered as requested in the RCE.

Claims 1, 6, 11, 17, 27, 30, 36, & 37 have been amended. Claims 1, 5-14, 17-21, 23-27, 29, 30, & 32-37 remain pending.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following claimed subject matte be shown or the feature(s) canceled from the claim(s):

A controller or control device; control display; hemodialysis machine; cordless interface and electrical communication for hemodialysis machine.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71 (a)-(c):

> (a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery

appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because applicant argues that the sensor does not contact blood. However, if no blood is contacted, how does the sensor detect blood loss? Further, Applicant's own specification, as originally filed, discloses that the sensor is in contact with an absorbent pad, which is holding blood, to detect wetness that is characteristic of blood or blood loss. Therefore, it appears that the disclosure is non-enabling for the invention claimed, since it is unclear how the invention functions based on the disclosure as filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-14, 17-21, 23-27, 29, 30, & 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter that the sensor does

not contact blood is not described in the specification as originally filed. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, & 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if applicant is intending to claim an additional pad in the claims with the language "further comprising a sterile pad" and the recited function. As a result of the amendments to claims 11 & 17, it appears that the sterile pad is a duplicate pad. Further, the use of both a barrier pad and a further sterile pad is not described in the specification or drawings. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-11, 13, 14, & 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (5,036,859). Brown discloses a moisture detector and indicator that may be used to sense the presence of blood (col. 9, lines 40-42). The detector

comprises electrodes (i.e. capacitive sensor) that is capable of detecting wetness due to blood, an absorbent material (i.e. barrier pad) that is capable of absorbing blood, and a cover sheet & backing layer (i.e. a holder) that are capable of holding the absorbent material and sensor over a needle. The detector is in communication with an indicator (i.e. control device) by means of electrical communication. The indicator receives a signal of wetness and alarms in response to the leak. Brown discloses that the electrodes (sensor) are separated from the body by the absorbent material, and the absorbent material soaks up upon a liquid if there is a leak to complete the circuit to activate the alarm. The sensor is further limited as being "capable of detecting wetness duet to blood" in the claims and it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson,* 69 USPQ 138. The recitation in the claims that the holder is "adapted to secure the sensor in juxtaposition to the needle" has not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. Therefore, the recitation that the needle be "venous" is also not positively recited and therefore not given any patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27 & 30 are rejected under 35 U.S.C. 103(a) as being obvious over Brown (5,036,859). Brown substantially discloses the invention as claimed, however, does not teach that the detector and indicator apparatus is used in a method of controlling blood loss from needle dislodgement, nor does Brown specifically teach the step of inserting a needle into a patient. Brown does teach that the apparatus may be used to detect blood loss, therefore, it would have been obvious to one having ordinary skill in the art use the apparatus adjacent to a needle in a patient they have inserted a needle into, since one of ordinary skill in the art would recognize that blood loss from a needle dislodgement could be very dangerous to the patient. Further, it would be

beneficial to use the apparatus over a needle to alert the user/physician if the needle should become dislodged, since it is important to quickly correct a needle dislodgement to avoid air infiltration of the vessel.

Claim 12 is rejected under 35 U.S.C. 103(a) as being obvious over Brown (5,036,859) in view of Bandeian, Jr. et al. (6,445,304). Brown substantially discloses the invention as claimed, however, does not teach that the detector and indicator apparatus electrodes are a single electrode plate. Bandeian, Jr. et al. discloses the use of an electrode plate (see figure 3) for use in an apparatus for detecting moisture, such as blood. At the time of the invention, it would have been an obvious matter of design choice to modify the two electrodes of Brown to be a plate electrode as taught by Bandeian, Jr. et al. as a substitution of parts, since applicant has set forth no criticality as to the structure and function of the electrodes being of a plate configuration.

Claims 23-26, 29, & 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (5,036,859) in view of Kjellstrand et al. (Aksys, LTD-WO99/24145). Brown discloses the invention substantially as claimed, see rejection supra, however does not specifically teach that the apparatus is used during hemodialysis wherein a venous needle is used. Kjellstrand et al. disclose an extracorporeal circuit having a blood line separation warning device. The extracorporeal circuit may be a dialysis machine, which further has a computer control and alarm circuit that has a display. The blood line separation warning device has

multiple electrodes connected via wires. Since Brown does teach that the apparatus may be used to detect blood loss, it would have been obvious to one having ordinary skill in the art use the apparatus, at the time of the invention, in a hemodialysis method, as taught by Kjellstrand et al., for detecting blood loss to immediately stop the procedure to avoid a catastrophic loss of blood.

Response to Arguments

Applicant's arguments filed 6/21/05 have been fully considered but they moot in view of the new ground(s) of rejection.

However, the objection to the drawings has not been withdrawn. It is clearly set forth in the drawings, under 37 CFR 1.83(a) that thee drawing must show every feature of the invention specified in the claims. However, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box). Without such a representation, it is not clear how the claimed limitations are related.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 25th, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3761

PATRICIA BIANCO
PRIMARY EXAMINER